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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,709	08/22/2001	Charles A. Morris	1533.0520001	6249

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,709	MORRIS ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 3-7-06 is acknowledged.

Claims included in the prosecution are 18-52.

Claim Rejections - 35 USC § 112

1. Claims 18-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vitamin E compositions, does not reasonably provide enablement for generic 'vitamin'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Instant invention is drawn to compositions, which are free flowing. The examples indicate the use of tocopherols. Though classified under the name 'Vitamins', compounds falling under this definition have different structures and different characteristics and stabilities. Furthermore, tocopherols used in examples are liquids as opposed to other vitamins such as A, K and B-complex vitamins and the process disclosed in the specification involves simple mixing of the components. . Applicant has not shown that the same free-flowing characteristics can be observed with all the compounds falling under 'vitamins' and which are solids.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that he has provided numerous examples in the specification that support the claims. This argument is not persuasive since the specification, which is only 7 pages, gives examples containing tocopherols and nothing else. As pointed out above, tocopherols are liquids as opposed to solid nature of other

vitamins. The declaration submitted is not persuasive since this shows only the preparation of the vitamin D3 and nothing indicates their free flowability.

2. In view of the amendment to claim 18, the new matter rejection is withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 19, 27 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant amends the independent claims 18 and 26 to recite 'fat soluble vitamin'. The vitamins vitamin C and various B vitamins recited in claims 19 and 26 are water-soluble vitamins and therefore, these claims are inconsistent with the parent claims.

It is unclear as to what applicant intends to convey by tocopherol containing vitamin in claim 51. What vitamin contains tocopherol? Tocopherol is the generic term used for various tocopherols.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 18-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al (4,486,435) in combination with Schmidt (4,603, 143).

Schmidt et al. teach a free-flowing, non-agglomerated, non-caking vitamin powder composition comprising about 45 to about 60 percent vitamin, about 2 to about I 8 percent of a water insoluble carrier, about 0.2 to about 2 percent hydrophobic silica, and other ingredients (c 8, 1 15-22). Schmidt et al. further teach that the water insoluble carrier can be corn starch (c 8, line 32). Schmidt et al. also teach that the vitamin can be selected from vitamin h, D, E, K and mixtures thereof as well as vitamin B1, B6, B2, B12, C and mixtures thereof (c 2, L 20-34). Lastly, Schmidt et al. teach that the vitamin composition of their invention is suitable for the preparation of tablets (c 1, L 49). Schmidt et al. do not teach that the vitamin is specifically mixed tocopherols. However, Schmidt et al. do teach that the vitamin can be selected from a group including vitamin E. Furthermore, applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, I 24-27). Therefore, it is the position of the examiner that based upon applicant's own admission, Schmidt's teaching of vitamin E suggests the limitations of the instant claims. The reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate

stability, or it would be useless for its intended purpose. What are lacking in Schmidt are the claimed particle sizes of silica.

As discussed before, Schmidt 143 while disclosing free flowing, high density, fat-soluble vitamin powder preparations teaches the use of silica of bigger particle sizes (abstract, Table 1, Examples and claims).

It would have been obvious to use the silica of bigger particle sizes in the compositions of Schmidt et al 435 with a reasonable expectation of success, since as evidenced by Schmidt 143, one can still obtain free flowing, high density and stable vitamin powders.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that 143 teaches away from adding cornstarch and silica. In support, applicant points out to col. 2, lines 39-42 which states that "the various processes of the prior art which involve the use of water and emulsifiers, such as gelatin and starch --- are unnecessary to the process of the invention. This argument is not persuasive since this statement only implies that if the process of preparation involves an emulsion process, then the water and emulsifiers such as gelatin and starch are not necessary. One could come to conclusion from this statement that one could include these if the process is an emulsification process. Furthermore, 143 only states that they are not necessary, but does not clearly state that these components SHOULD NOT be included at all. Applicant argues that 435 teaches the use of cornstarch but only in the context of ulrafine aerosolized silica for encapsulating spray dried particles of riboflavin and starch. This argument is not persuasive since the location pointed out by applicant

(col. 5, line 65) shows the preparation of riboflavin powders as an example and this does not mean that starch should not be used when the other vitamin powders are prepared. Furthermore, instant claims recite various B vitamins. Applicant points out to col. 4, lines 21 and 24-29 and argues that 435 patent teaches that such silica particles must be ultrafine to encapsulate the riboflavin and starch. This argument is not persuasive since applicant has not shown any unexpected results by using bigger particles of silica as opposed to the fine particles. Furthermore, as applicant himself recognizes this statement pertains to silica particles when used in combination with riboflavin and not when used with other vitamins. The rejection is maintained.

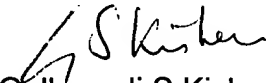
5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK